**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| **KRISTEN A. BULL** | **CIVIL ACTION** |
| **v.** | **NO. 17-1141** |
| **ST. JUDE MEDICAL, INC.,** | |

**Baylson, J.** **July 12, 2018**

**MEMORANDUM RE: MOTION TO DISMISS**

## I. Introduction

In this case, Plaintiff Kristen Bull alleges that Defendant St. Jude Medical, Inc. committed negligence by failing to warn her physicians about risks inherent in a medical device it manufactured, the Riata ST Lead, a component part of a medical device that was implanted in Plaintiff's heart. Plaintiff asserts that St. Jude was aware of instances in which the Riata ST Lead malfunctioned, creating danger to patients, and that it did not inform the FDA about all of these instances in violation of its specific duty to do so under relevant federal regulations. Plaintiff brings one common law tort cause of action against St. Jude. Presently before the Court is a Motion to Dismiss the Amended Complaint for failure to state a claim for which relief can be granted, filed by St. Jude. For the reasons discussed below, Defendants' motion is denied.

## II. Factual History

Taking Plaintiff's allegations as true, the factual background is as follows. Defendant St. Jude manufactures a medical device known as an implantable cardiac defibrillator ("ICD"), which is used to treat heart conditions. (Amended Complaint, ¶ 7.) Specifically, an ICD can correct slow heart rates, pace rapid heart rates, and administer a shock to stabilize the heart and allow for a return to an appropriate rhythm. (Id., ¶ 11.) Wires, called leads, connect an ICD to the muscle on the inside of the heart. (Id., ¶ 7.) Leads conduct electrical impulses between the heart and the ICD. (Id., ¶ 12.) High voltage leads are inserted through a major vessel and

attached directly to the muscle on the inside of the heart. (Id.) Electrodes that sense the heart's rhythm are built into the leads via cables and conductors, and are positioned in the heart for the purpose of monitoring the heartbeat and correcting any irregular rhythms by transmitting electric shocks from the ICD when necessary. (Id., ¶¶ 7, 12.) If the ability of the lead to sense or transmit electrical signals is compromised, the ICD will fail to perform properly. (Id., ¶ 13.) Types of lead failures include externalization of the conductors, abrasion, fractured wires, cables, or conductors, insulation loss, loss of ability to capture changes in electrical characteristics in the ventricle chamber, abnormal lead impedance, sensing failure, and changes in tissue conductor interface. (Id.)

**A. Initial and Supplemental Pre-market Approval, and Medical Device Reporting**

St. Jude Riata Leads are Class III medical devices. (Am. Compl., ¶ 16.) A pre-market approval application ("PMA") must be submitted to the FDA for any Class III medical device. (Id., ¶ 14.) A PMA must contain particular information that is reviewed by the FDA to determine the safety and efficacy of the device. (Id.) PMA Supplements are supplemental applications to an approved PMA seeking approval of a change or modification in a Class III medical device. (Id., ¶ 21.) Pursuant to 21 C.F.R. § 814.3(g), PMA supplements include "all information submitted with [the PMA Supplement] or incorporated by reference therein." (Id., ¶ 22.)

In 1996 the FDA approved St. Jude's PMA for the Ventritex TVI Lead, the predecessor of the Riata and Riata ST Leads. (Id., ¶¶ 8, 16.) St. Jude was required to, and did, "establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met" consistent with 21 C.F.R. § 820.30. (Id., ¶ 18.) Pursuant to 21 U.S.C. § 360(h), St. Jude was required to be, and was, inspected by the FDA "at least once in the 2-year

period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter." (Id., ¶ 20.)

The Riata Leads were introduced to the U.S. market in 2002. (Id., ¶ 8.) FDA approval for these leads was based on fourteen supplements to St. Jude's 1996 submission for approval of the Ventritex TVI Lead, submitted between 1996 and 2002. (Id., ¶¶ 8, 22.) These supplements altered various aspects of the design and manufacture of the leads. In March 2006, the FDA approved changes to the Riata Leads. (Id., ¶ 23.) The devices as modified are marketed under different trade names, one of which is Riata ST Model 7042, the model used in the ICD implanted in Plaintiff's heart. (Id.)

The FDA relies on Medical Device Reporting ("MDR") to receive information about significant medical device adverse events from manufacturers, importers, and user facilities, so that problems can be corrected quickly. (Id., ¶ 49.) The FDA publishes the adverse events and MDRs in a public, searchable database called MAUDE which is updated monthly. (Id., ¶ 50.) The general public, including physicians and patients, uses the MAUDE database to obtain safety data on medical devices. (Id.) Full and complete reporting of adverse events is required of all manufacturers by the FDA. (Id., ¶ 51.) This reporting serves to notify the public that a potential problem with a device exists, and can prompt an informed person or organization to develop a solution. (Id.)

### B. 2009 FDA Quality Systems Inspection Technique and Resulting Establishment Inspection Report

In 2009 the FDA conducted a for-cause Quality Systems Inspection Technique ("QSIT") of St. Jude's manufacturing facility in Sylmar, California. (Am. Compl., ¶ 24.) As part of this inspection, the FDA required St. Jude to provide a list of all Corrective and Preventive Action ("CAPA") and Product Improvement Requests ("PIRs") opened since 2002, and St. Jude

reported fourteen PIRs regarding High Voltage Leads. (Id.) The inspection revealed that St. Jude had deficiencies in the handling of complaints, making MDR determinations, CAPA procedures, and receiving protocols. (Id., ¶ 25.)

St. Jude provided a spreadsheet during the investigation indicating that between 2002 and 2009, the company had received 8,463 complaints regarding the Riata and Durata lead models, and that for all complaints identified as "perforation, patient," an MDR was submitted. (Id., ¶ 28.) However, the FDA adverse event database contained only 3,689 MDRs from St. Jude for the Riata and Durata lead models during this same time period. (Id.) The inspection revealed that in some cases in which complainants reported perforation adverse events associated with the Riata and Durata devices, St. Jude did not report "perforations" in the associated MDRs submitted to the FDA, and did not identify "perforation" in Form 3540A submissions in either the patient or device problem codes. (Id., ¶ 31.) Eight complaints from the MAUDE database, that were identified by St. Jude as "capture anomaly," "dislodgment," or "patient discomfort," were reviewed and the investigation concluded that six of these eight "in fact described a suspected perforation and it could not be ruled out as possible for the other two events." (Id., ¶ 32.)

The 2009 Establishment Inspection Report also notes that "complaints representing events that are MDR reportable were not promptly reviewed, evaluated and investigated by the designated individual per 21 C.F.R. § 820.198(d), and MDRs were not submitted within the mandatory reporting timeframes required by 21 C.F.R. § 803.50 for device manufacturer." (Id., ¶ 33.) The report also states that review of the MDRs submitted from 2007 through June 2009 concluded that there was no evidence that the perforation events described in the medical or scientific literature were submitted to the FDA as required by regulations and company

procedures. (Id., ¶¶ 34, 40.) The 2009 inspection also revealed that St. Jude failed to follow their procedure for product design developments of the Leads. (Id., ¶ 35.)

As a result of these deficiencies the FDA issued an eight-item FDA-483 report on July 8, 2009. (Id., ¶ 36.) An FDA Form 483 is issued to management at the conclusion of an inspection when an investigator has observed any conditions that in their judgment may constitute violations of the Food, Drug, and Cosmetic Act and related Acts. (Id.) The eight deficiencies identified in the report are as follows:

1. St. Jude failed to include all information that was reasonably known to the manufacturer on an MDR report in violation of 21 C.F.R. § et seq.

2. St. Jude failed to timely submit MDRs to the FDA and such submissions were significantly past the mandatory reporting timeframes without written explanation in violation of 21 C.F.R. § 803 et seq.

3. St. Jude failed to define the procedures for implementing corrective and preventative actions in violation of 21 C.F.R. § 820 et seq.

4. St. Jude failed to review their sampling methods for adequacy of their intended use in violation of 21 C.F.R. § 820 et seq.

5. St. Jude failed to perform design reviews at appropriate times in violation of 21 C.F.R. § 820 et seq.

6. St. Jude failed to perform a complete risk analysis in violation of 21 C.F.R. § 820 et seq.

7. St. Jude failed to establish procedures for the validation or verification review, and approval of design changes before their implementation in violation of 21 C.F.R. § 820 et seq.

8. St. Jude failed to resolve discrepancies noted at the completion of design verification in violation of 21 C.F.R. § 820 et seq.

(Id., ¶ 37.) The Establishment Inspection Report states that "complaints representing events that are MDR reportable were not promptly reviewed, evaluated, and investigated by the designated individual per 21 C.F.R. § 820.198(d)." (Id., ¶ 38.)

The report also states that St. Jude's Standard Operating Procedure for Global Risk Management was inadequate as it related to "clinical risk in new product development and throughout the product life cycle, and [was] inadequate in that the procedure did not establish a methodology for obtaining a Probability of Occurrence used in Risk Evaluations." (Id., ¶ 41.)

**C. 2011 FDA Safety Officer Report**

A 2011 report by an FDA safety officer notes that St. Jude's CAPAs limited the analysis to "externalized cables and [did] not include exposed cables or all other forms of abrasion, which FDA considers important contributors to the published rate of all abrasion presented in [St. Jude's] November 2011 Product Performance Report (PPR)." (Am. Compl., ¶ 44.) It goes on to say that the "published failure rate based on PPR is based only upon reported events and returned product analysis, and therefore underestimates the actual rate of occurrence." (Id.) The 2011 Report also notes numerous instances of underreporting and states that the terms "'externalized cable' or even 'abrasion' may not be employed when it is a contributing cause to the reporter having been unaware that externalized cable occurred. The clinical presentation (noise, inappropriate therapy, no therapy, etc.) may be what is reported and not the diagnosis of the lead mechanical failure." (Id., ¶ 46.)

The 2011 report further notes that while St. Jude reported "only one (1) instance of 'inappropriate high voltage shock delivery,' the Office of Science and Engineering Laboratories' (OSEL) analysis from last January counted 71 cases of inappropriate shock, noise, and/or over sensing (out of 172 inside-out abrasion cases)." (Id., ¶ 47.) OSEL further found that "nine out of the first ten instances reviewed for these three events were referred to as 'inappropriate therapy," thus, OSEL concluded that St. Jude "may under-estimate the actual number of inappropriate shocks due to their limiting terminology." (Id.) The 2011 report also noted that "OSB identified

a total of 794 reports of insulation abrasion, and 116 of those reports mentioned inside-out abrasion," and notes that "the reports submitted by [St. Jude] to FDA concerned externalized cables and abrasion failures are not up to date." (Id., ¶ 48.)

**D. 2012 483 Inspection**

On October 17, 2012, the FDA conducted a subsequent 483 inspection of St. Jude's Sylmar manufacturing facility and identified several deficiencies including failures regarding design verification, complaint handling, CPA procedures, risk analyses, inspection/measuring/testing/calibration of equipment, document control, and employee training. (Am. Compl., ¶ 52.)

**E. Dear Doctor Letters and 2011 Recall**

On December 15, 2010, St. Jude published a "Dear Doctor" letter ("2010 letter") indicating that issues with defects in the insulation were identified in several Riata Lead Models, including the model used in Plaintiff's ICD, number 7042. (Am. Compl., ¶ 53.) The 2010 letter stated that "the Riata and Riata ST Family of Silicone Leads have exhibited an insulation abrasion rate of 0.47% over nine years of use," and noted that the silicone used on these leads was "vulnerable to abrasion." (Id., ¶ 54.) The 2010 letter indicated that lead insulation abrasion had been associated with over-sensing, under-sensing, loss of capture, changes in pacing and/or high voltage lead impedances, and inability to deliver high voltage therapy. (Id., ¶ 55.) St. Jude did not initiate a voluntary recall of the Riata Leads at the time the letter was published, but instead stated in the 2010 letter that it was "phasing out" all Riata Lead models by the end of 2010. (Id., ¶ 57.) It also stated that its Medical Advisory Board did not recommend explant of the affected leads, but rather that patients with these leads be monitored. (Id., ¶ 58.)

On November 28, 2011, St. Jude issued a second Dear Doctor letter ("2011 letter") relating to the same set of Riata Lead models as the 2010 letter. (Id., ¶ 59.) The 2011 letter stated that the failure rates for these Riata Leads had increased from the 2010 rate of 0.47% to 0.63%. (Id., ¶ 60.) The 2011 letter continued to recommend monitoring patients and did not initiate a voluntary recall. (Id.)

On December 21, 2011 the FDA reclassified St. Jude's Dear Doctor letters to a Class 1 Recall, which is the most serious level of recall and is defined as a situation in which there is a reasonable probability that the use of or exposure to a product will cause serious adverse health consequences or death. (Id., ¶¶ 62-63.) The FDA explained that the reason for the recall was that "failures associated with lead insulation abrasion on the St. Jude Riata and Riata ST Silicone Endocardial Defibrillation Leads may cause the conductors to become externalized." (Id., ¶ 64.)

**F. Other Allegations of Unreported Lead Failures**

Doctors reported Riata Lead failures over the course of several years prior to St. Jude making any public statement on this issue. As early as 2006 doctors had reported to St. Jude inside-out abrasion incidents involving the silicone insulation and constriction of the Riata Leads. (Am. Compl., ¶ 77.) Between March, 2010 and July, 2010, St. Jude received reports of at least six deaths caused by electrical malfunctions in the Riata Leads. (Id., ¶ 76.) An October, 2012 article published in the Wall Street Journal reflected additional examples of reporting of Riata Leads failures for years prior to St. Jude's public statements in 2010 and 2011. (Id., ¶ 79.) The article reported that between 2006 and 2009 three doctors from three different hospitals had encountered abrasion in the Riata Leads, however when they informed St. Jude they were told by company officials that the incidents were isolated. (Id.) The article further reported that St. Jude conducted an internal audit examining multiple instances of lead failures related to abrasion

before April, 2008. (Id., ¶ 80.) The article stated that this 2008 audit concluded that the Riata Leads had "potentially serious insulation problems including inside-out abrasion." (Id., ¶ 81.)

**G. Plaintiff Kristen Bull's ICD Malfunction**

On or about November 1, 2010, Plaintiff Kristen Bull underwent a surgical procedure at the Hospital of the University of Pennsylvania to have a St. Jude ICD with Riata ST Leads implanted. (Am. Compl., ¶ 85.) The Riata Leads are attached to the ICD and inserted through a major vein and attached directly to the muscle on the inside of Plaintiff's heart. (Id., ¶ 86.) The 2010 letter was published one month after Plaintiff's ICD implantation, and in reliance on the advisory contained in the 2010 letter, Plaintiff's physicians placed her on a monitoring program rather than explanting the device. (Id., ¶ 87.) On October 11, 2015, Plaintiff was on an airplane sitting on the tarmac at an airport in South Carolina when her ICD malfunctioned and fired six times. (Id., ¶ 92.) Plaintiff was transported and admitted to the Grand Strand Regional Medical Center where she spent the night, however the hospital was not equipped to deactivate the ICD. (Id., ¶ 93.) The next morning a St. Jude representative came to the hospital to deactivate her ICD, and Plaintiff was placed in a Life Vest. (Id., ¶ 94.)

Plaintiff's husband flew to South Carolina to drive her back to Philadelphia, because Plaintiff was afraid to be in an airplane in case of further complications. (Id., ¶ 96.) On October 28, 2015, Plaintiff was admitted to the Hospital of the University of Pennsylvania, and after being observed overnight underwent surgery for explanation of her St. Jude ICD, and implantation of a new ICD. (Id., ¶¶ 97-98.) Before deactivation and explantation of her St. Jude ICD, Plaintiff experienced three instances of insulation abrasions to her Riata ST Lead, two external and one internal. (Id., ¶ 100.)

Many of the untimely and inadequate reports concerned abrasion-related defects, including externalization of cables, perforation, inappropriate therapy, sensing problems, and inside-out abrasion. (Id., ¶ 106.) Plaintiff's lead suffered failure causing abrasion and externalization, which are defects that St. Jude was aware of but did not properly and timely report to the FDA. (Id., ¶ 107.) Had St. Jude properly and timely reported these adverse events to the FDA, information regarding the risks of the Riata Leads would have reached Plaintiff's treating medical professionals in time to prevent her injuries, as they would have chosen not to use the Riata ST Lead but would have instead selected another ICD with another lead. (Id., ¶¶ 108-109.) If St. Jude had reported the findings of its 2008 audit, Plaintiff's physician would not have chosen the Riata ST lead. (Id., ¶ 110.)

## III. Procedural History

Plaintiff filed the original Complaint in this case on March 15, 2017 (ECF 1). On June 5, 2017 Defendant filed a Motion to Dismiss Plaintiff's Complaint (ECF 6). Plaintiff responded on July 7, 2017 (ECF 12), and Defendant replied on July 14, 2017 (ECF 13). The Court held oral argument on the original Motion to Dismiss on October 17, 2017, and based on representations made in court, gave Plaintiff several weeks to either file amended pleadings or voluntarily dismiss the Complaint. Plaintiff filed an Amended Complaint on December 11, 2017 (ECF 18) alleging one cause of action, a Pennsylvania common law Negligence claim on a Failure to Warn theory, based on St. Jude's failure to accurately, and in a timely manner, report all adverse events relating to the Riata Leads to the FDA via MDRs for inclusion in the MAUDE database. Defendant then filed a Motion to Dismiss the Amended Complaint on January 29, 2018 (ECF 23). Plaintiff responded on February 23, 2018 (ECF 25) and Defendant replied on March 13, 2018 (ECF 28).

## IV. Legal Standard

In considering a motion to dismiss under Rule 12(b)(6), the Court must accept as true all well-pleaded allegations in the complaint and view them in the light most favorable to the plaintiff. Angelastro v. Prudential–Bache Sec., Inc., 764 F.2d 939, 944 (3d Cir. 1985). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)).

The Court in Iqbal explained that, although a court must accept as true all of the factual allegations contained in a complaint, that requirement does not apply to legal conclusions; therefore, pleadings must include factual allegations to support the legal claims asserted. Id. at 678, 684. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. at 678 (citing Twombly, 550 U.S. at 555); see also Phillips v. County of Allegheny, 515 F.3d 224, 232 (3d Cir. 2008) ("We caution that without some factual allegation in the complaint, a claimant cannot satisfy the requirement that he or she provide not only 'fair notice,' but also the 'grounds' on which the claim rests.") (citing Twombly, 550 U.S. at 556 n.3). Accordingly, to survive a motion to dismiss, a plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678 (citing Twombly, 550 U.S. at 556).

## V. Discussion

St. Jude argues that Plaintiff's claim is both expressly and impliedly preempted by federal law, and that it is inadequately plead. The Court will take each of Defendant's arguments in turn.

### A. Express Preemption

### i. Defendant's Contentions

St. Jude asserts that Plaintiff's claim is expressly preempted by the Medical Device Amendments of 1976, 21 U.S.C. § 360k(a), as interpreted by Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). Under Riegel, St. Jude argues, a state law tort claim must assert "parallel," that is identical, requirements on the manufacturing of a medical device in order to avoid preemption by federal law. Defendant's Motion to Dismiss at 12-13. Plaintiff's allegation that St. Jude had a state law duty to warn physicians about deficiencies of the Riata Leads describes a different requirement on St. Jude than that imposed by federal law, namely, the duty to report adverse events to the FDA in the form of MDRs, which are not even necessarily disclosed to physicians or the general public and have limited significance as compared with typical warnings to physicians. Def.'s Mot. at 14-16. Pennsylvania's "sophisticated user" doctrine, St. Jude adds, neither requires nor is satisfied by the duty to report adverse events to the FDA—these duties are not synonymous nor do they seriously overlap. Def.'s Mot. at 16-17.

### ii. Plaintiff's Contentions

Plaintiff responds that there is a general presumption against preemption. Plaintiff's Brief in Response to Defendant's Motion at 4-5. Plaintiff argues that her state law failure to warn claim, which consists of allegations that St. Jude violated federal law by failing to comply with reporting requirements, identifies violations of state duties that parallel, rather than add to, these federal requirements, and thus that her claim is not expressly preempted. Pl.'s Br. at 5-8. The Pennsylvania state law requirement that manufacturers warn third parties about the dangers of their products is well established, Plaintiff asserts. Pl.'s Br. at 10-11. This duty is governed by the "learned intermediary doctrine," and is not different from nor does it add to the federal duty to report adverse events to the FDA via MDRs. Pl.'s Br. at 11-13.

### iii. Applicable Law and Analysis

The Medical Device Amendments of 1976, 21 U.S.C. § 360k, ("MDA") explicitly forbids state laws that impose requirements for medical devices and their manufacturers that are "different from, or in addition to" requirements set forth in the FDCA, and "which relate[] to safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA]." 21 U.S.C. § 360k(a)(1). In Riegel v. Medtronic, Inc., the Supreme Court set out a two-part test to determine under what circumstances this preemption clause bars common law claims for damages caused by medical devices. Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). All Class III medical devices must go through the FDA's Pre-Market Approval ("PMA") process in order to enter the market; devices which have successfully made it through this process must be produced and marketed in accordance with standards determined in the course of the PMA process. These device-specific standards are referred to as "PMAs." Another condition of PMA approval is that manufacturers must comply with ongoing Medical Device Reporting ("MDR") requirements for all Class III medical devices. § 360i(a)(1). Specifically, a manufacturer must report instances in which it "receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices (A) may have caused or contributed to a death or serious injury, or (B) has malfunctioned and…would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." § 360i(a)(1(A)-(B).

Under Riegel a court must first determine "whether the Federal Government has established requirements applicable" to the device at issue; if so, a court must then evaluate "whether the [ ] common-law claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and

effectiveness." Riegel, 552 U.S. at 321-322. The Court concluded that for Class III medical devices which have successfully made it through the PMA process the first prong is automatically satisfied. In evaluating the second prong the Court clarified that common law duties do constitute state "requirements" and thus can be preempted. Riegel, 552 U.S. at 324. State law claims that are "premised on a violation of FDA regulations" will not be preempted, however, because "the state duties in such a case 'parallel,' rather than add to, federal requirements." Riegel, 552 U.S. at 330 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996)).

As a Class III, FDA-approved medical device, the Riata ST Lead was approved through the PMA process, as outlined in the Amended Complaint. The first prong of Riegel is thereby automatically satisfied. Our analysis of express preemption will thus focus on the second prong: whether Plaintiff's failure to warn claim identifies a state requirement with respect to the Riata ST Lead that is "different from, or in addition to" federal requirements related to the safety and effectiveness of the Riata ST Lead.

Under Pennsylvania law, a failure to warn theory requires a Plaintiff to demonstrate that "the product [was] distributed without sufficient warnings to notify the ultimate user of the dangers inherent in the product." Wright v. Ryobi Technologies, Inc., 175 F.Supp.3d 439, 453 (E.D. Pa. 2016) (citing Phillips v. A–Best Prods. Co., 665 A.2d 1167, 1171 (1995)). In Pennsylvania, the "learned intermediary doctrine" governs failure to warn claims relating to prescription drugs and medical devices. Creazzo v. Medtronic, Inc., 903 A.2d 24, 32 (Pa. Super. Ct. 2006) (holding the learned intermediary doctrine applies in the context of medical devices, just as it does in the context of prescription drugs); see also, Hricik v. Stryker Biotech, LLC, et al., 89 F.Supp.3d 694, 703 (E.D. Pa. 2015). Under this doctrine, "a manufacturer will be held

liable only where it fails to exercise reasonable care to inform a physician of the facts which make [a medical device] likely to be dangerous." Cochran v. Wyeth, Inc., 3 A.3d 673, 676 (Pa. Super. Ct. 2010). Plaintiff alleges that by failing to comply with the federal MDR regulations, St. Jude violated this specific Pennsylvania duty to warn. The question, then, is whether, in the context of these allegations, the Pennsylvania duty on manufacturers to warn physicians of the dangers inherent in a medical device is "parallel" to the federal duty on manufacturers to report adverse events relating to a medical device to the FDA in the form of MDRs.

Most courts to have considered the question have concluded that state law tort claims premised on allegations of violations of federal regulatory frameworks, such as the MDR reporting framework—as Plaintiff's claim is framed—"parallel" rather than add to federal law and are therefore not expressly preempted by the MDA as interpreted in Riegel. See, e.g., Bass v. Stryker Corporation, 669 F.3d 501, 512 (5th Cir. 2012) (allegations that a manufacturer failed to comply with PMAs, or other FDA regulatory schemes, are legitimate bases to make out a parallel claim); Bausch v. Stryker Corporation, 630 F.3d 546, 549; 560-61(7th Cir. 2010) (Plaintiff's manufacturing defect claims were not subject to dismissal on preemption grounds at the pleading stage where the Complaint alleged generally that her Class III medical device "failed to comply with federal standards."); Hofts v. Howdmedica Osteonics Corp., 597 F.Supp.2d 830, 836-838 (S.D. Ind. 2009) (holding that allegations that in manufacturing the Class III medical device at issue defendant did not satisfy the FDA's PMA standards were sufficient to plead a parallel claim under the MDA).

The Fifth Circuit reached this conclusion with respect to a state failure to warn claim based on allegations that a manufacturer failed to comply with MDR reporting requirements, similar to those at issue here:

> [Plaintiff's] claim is not expressly preempted to the extent she asserts that [Defendant] violated the state duty to warn by failing to accurately report serious injuries and malfunctions of the [medical device] as required by the FDA's MDR regulations. The MDR regulations are related to the manufacturer's duty to provide the FDA with information regarding a device's safety and effectiveness, and this information is disseminated to the public. A factfinder could infer that a manufacturer's failure to provide this information as required by FDA regulations is a parallel violation of the state duty to provide reasonable and adequate information about a device's risks.

Hughes v. Boston Scientific Corp., 631 F.3d 762, 770-71 (5th Cir. 2011). This reasoning is sound, and this Court reaches the same conclusion here: Plaintiff's state law failure to warn claim identifies a state duty to warn physicians of risks inherent in medical devices that is parallel to St. Jude's duty to comply with MDR reporting requirements with respect to the Riata ST Lead, a Class III medical device that has received premarket approval. The Amended Complaint adequately states this theory, including allegations of specific instances in which St. Jude had particular information that it was allegedly required to but did not report, as recounted in the 2009 Establishment Inspection Report, and in the media. The state law duty that forms the cause of action does not extend beyond that required of St. Jude under federal MDR regulations. As such, it parallels these federal requirements, and is not expressly preempted.

**B. Implied Preemption**

**i. Defendant's Contentions**

St. Jude also argues that Plaintiff's claim is impliedly preempted under 21 U.S.C. § 337(a), which states that any action to enforce the FDCA "shall be by and in the name of the United States," as interpreted in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001). Only state law claims that would exist independent of the existence of the FDCA can survive implied preemption, and Plaintiff's claim that St. Jude failed to report adverse events by filing MDRs with the FDA clearly does not fit that description. Def.'s Mot. at 18-19.

### ii. Plaintiff's Contentions

Plaintiff argues that state tort law claims are only impliedly preempted under Buckman in very limited circumstances where a "fraud on the FDA" theory is alleged. Pl.'s Br. at 21-24. Plaintiff explains that she is alleging that St. Jude breached a duty to warn owed to consumers, not to the FDA, and that this allegation depends on "traditional state tort law principles" not implicated by Buckman preemption. Pl.'s Br. at 25.

### iii. Applicable Law and Analysis

In Buckman, the Supreme Court held that state law "fraud on the FDA" claims "conflict with, and are therefore impliedly pre-empted by federal law." Buckman, 531 U.S. at 348. The essence of the conflict giving rise to implied preemption in this context is the way in which state tort law claims for fraud on the FDA would interfere with the FDA's ability to carefully maintain and pursue its complex goals in enforcing the FDCA and the MDA—permitting state law tort claims would inappropriately increase and complicate the burdens faced by medical device manufacturers seeking approval under the FDCA and the MDA, with the effect of undermining the FDA's ability to enforce these regulatory regimes in a manner consistent with its priorities. "The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law." Buckman, 531 U.S. at 348. Importantly, the fraud claims at issue in Buckman "exist solely by virtue of the FDCA disclosure requirements," and the Court distinguished this type of claim from those state law claims "that parallel federal safety requirements" and which might be

allowed—specifically, those that rely "on traditional state tort law which [ ] predate[s] the federal enactments" at issue. Id., at 353.

State law claims that allege liability based on a common law tort theory and which parallel federal law claims, then, are not impliedly preempted under Buckman. To survive dismissal via preemption the Amended Complaint thus must allege "conduct that violates [federal law, or else Section 360k(a) expressly pre-empts the claim,] ... but the plaintiff must not be suing *because* the conduct violates federal law, because he has no private right to bring such a claim." In re Medtronic, Inc. v. Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010). In other words, "section 360k protects a medical device manufacturer from liability to the extent that it has complied with federal law, but it does not extend protection from liability where the [state tort] claim is based on a violation of federal law." Bausch v. Stryker Corp., 630 F.3d at 552. That is the situation we have here. Plaintiff has alleged that St. Jude violated state tort law, namely, by failing to warn physicians about the risks of the Riata ST Lead *based on* the failure to fully comply with its federal duty to report all adverse events to the FDA via MDRs in a timely manner. It is because of this simple fact—that Plaintiff's cause of action is a traditional state failure to warn theory premised on alleged non-compliance with federal regulations—that it is not impliedly preempted under Buckman. Plaintiff's claim survives implied preemption in addition to express preemption.

**C. Adequacy of the Pleadings**

**i. Defendant's Contentions**

Finally, St. Jude argues that even if Plaintiff's claim was not preempted, it would be subject to dismissal for failure to state a plausible claim for relief. Def.'s Mot. at 2. Plaintiff fails to allege a specific enough causal connection between the allegations that St. Jude failed to

report adverse events to the FDA and Plaintiff's alleged injuries. Def.'s Mot. at 21-23. Plaintiff does not even allege that her doctors consulted the MAUDE database, or any other source of MDRs or other adverse event reports, when making their treatment decisions. Def.'s Mot. at 27. Further, Plaintiff's allegations relating to St. Jude's failure to report adverse events involving perforations are irrelevant to her claim that she was injured as the result of insulation abrasion, as Plaintiff has not alleged any connection between the two phenomena, and Plaintiff fails to allege that St. Jude failed to report incidents of insulation abrasion. Def.'s Mot. at 24. Thus Plaintiff's claim is not plausibly plead.

**ii. Plaintiff's Contentions**

Plaintiff responds that the Amended Complaint meets the pleading standards necessary to survive a Motion to Dismiss in that it alleges multiple specific failures on the part of St. Jude to report incidents of lead failures to the FDA. Pl.'s Br. at 27-32. Moreover, the Amended Complaint alleges that these specific failures by St. Jude to warn the FDA of adverse events caused Plaintiff's injuries. Pl.'s Br. at 32. This is sufficient, as Plaintiff is not required at the pleading stage to state definitively what her doctor's would have done if St. Jude had properly reported all adverse events, but rather, it is enough that Plaintiff has alleged that prior to the implantation of her ICD St. Jude failed to disclose adverse events that, if disclosed, would have led Plaintiff's doctors to not use the Riata Lead. Pl.'s Br. at 33-34.

**iii. Applicable Law and Analysis**

In order to make out a successful failure to warn theory, the evidence must establish two elements: "(1) the product was sold in a defective condition unreasonably dangerous to the user, and (2) the defect caused the plaintiff's injury. To establish that a product was defective, a plaintiff must show that a warning of a particular danger was either inadequate or altogether

lacking, and that this deficiency made the product unreasonably dangerous. To establish causation, a plaintiff must demonstrate that he would have avoided the danger had he been warned of it by the seller." Ryobi Technologies, 175 F.Supp.3d at 453-54 (citing Phillips v. A–Best Prods. Co., 665 A.2d at 1171).

The Amended Complaint adequately states a claim that the Riata ST Lead was defective on a failure to warn theory, in that it alleges that St. Jude was aware of adverse events associated with the Riata ST Lead—instances in which it malfunctioned and posed a danger to patients—that it did not warn the FDA and the general public about, thereby putting potential users at risk from the danger it posed. Plaintiff also plausibly alleges the requisite causal nexus between St. Jude's alleged violation of this duty to report adverse events via MDRs, and Plaintiff's injury. Plaintiff alleges that the information included in MDRs is made publicly available and utilized by physicians in making treatment decisions regarding Class III medical devices. Plaintiff alleges that if St. Jude had made timely and complete MDR reports of all adverse events that it was aware of prior to the implantation of her ICD on November 1, 2010, her physicians would not have chosen to implant an ICD using Riata ST Leads, and instead would have chosen another such device using different leads. This sufficiently alleges a claim that if she had been warned about the deficiencies with the Riata ST Lead, then she would have avoided being injured by it.[1] Plaintiff is not required to make any further allegations at the pleading stage.

[1] In conducting research on the general topic of causation in these cases, the Court has reviewed a number of decisions in other jurisdictions on similar facts. Several cases which determine that allegations of causation, similar to Plaintiff's, were sufficient are: Rosen v. St. Jude Med., Inc., 41 F. Supp. 3d 170 (N.D.N.Y. 2014) (holding that a generalized allegation that PMAs were deviated from—as opposed to a specific allegation that a particular PMA was violated—is sufficient to plead causation at the Motion to Dismiss stage); Waltenburg v. St. Jude Med., Inc., 33 F. Supp. 3d 818 (W.D. Ky. 2014) (holding that failure to warn and manufacturing defect claims were plead with sufficient particularity where the Complaint merely alleged that St. Jude failed to comply with federal regulations, and did not include details regarding specific PMA requirements); cf., Franzese v. St. Jude Med., Inc., 2014 WL 2863087 (E.D.N.Y. 2014) (holding that Complaint did not adequately state causation necessary for failure to warn

## I. Conclusion

The Court had initially scheduled oral argument in this case on the Motion to Dismiss the Amended Complaint, and submitted a few questions of general interest to counsel for the oral argument. Scheduling the oral argument has become impossible in the time frame acceptable to the Court and has therefore been canceled. The Court concluded that it can fairly decide the Motion to Dismiss the Amended Complaint without specific answers to the questions. Some of the topics in the questions can be answered during discovery or in subsequent motion practice.

For the reasons stated herein, Defendant's Motion will be denied.[2]

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claim because it failed to allege that St. Jude was aware of any risks associated with leads *prior to* Plaintiffs having them implanted, and merely alleged risks that came to light three years later).